Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FDA Oversight of State Food Firm Inspections

A Call for Greater Accountability

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EXECUTIVE SUMMARY

PURPOSE

To assess the Food and Drug Administration's oversight of food firm inspections conducted by States through contracts and partnership agreements.

BACKGROUND

Inspections as a Key to Food Safety

The World Health Organization recently estimated that up to 30 percent of people living in industrialized countries may suffer from foodborne illnesses each year. In the United States, the Centers for Disease Control and Prevention recently estimated that foodborne diseases cause about 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. The annual cost of foodborne illness in the United States is estimated to be between $7.7 and $23 billion.

The Food and Drug Administration (FDA) plays a key role in overseeing the nation's food supply. It is responsible for the oversight of most foods involved in interstate commerce, with the major exceptions of meat and poultry. Under the Federal Food, Drug, and Cosmetic Act, the FDA's primary role in food safety is to inspect the conditions under which food is manufactured, processed, packed, and stored. The States also play a critical role in overseeing the nation's food supply. State and local governments conduct the majority of inspections in the U.S., including food retailers, manufacturers, processors and distributors within their State boundaries in accordance with their own laws and authorities.

Over the past 25 years, FDA has extended its inspection coverage by utilizing the resources and expertise in the States to fulfill its responsibility. For many years, FDA relied on contract arrangements, through which FDA paid the States to conduct inspections in accord with Federal regulations. In recent years, FDA has initiated partnership agreements with a number of States. Under these arrangements, the States agree to conduct inspections under their own authorities, without Federal funding, and to share the results with FDA. An effective food safety system depends on the collective efforts and coordination among Federal, State and local levels of government.

FDA Oversight as a Key to Accountability

In recent years, groups including the National Academy of Sciences, the Association of Food and Drug Officials, industry trade associations, consumer groups, and the States

themselves have recognized the importance of strong Federal oversight of State food firm inspections. Such oversight is essential to assure consumers that necessary food safety protections are in place, and to assure domestic industries and international trading partners that the FDA is committed to the quality and uniformity of food safety regulation.

This Inquiry

In this report, we begin by reviewing three fundamental factors that underscore the importance of FDA oversight of State inspections conducted through contracts and partnership agreements. We then turn, in more depth, to assess the adequacy of that oversight system. We draw on a variety of sources in this inquiry, including analysis of FDA inspection data, national surveys, site visits, observations of FDA audits, reviews of the State contracts and partnership agreements, reviews of year-end evaluations, and interviews with industry, consumer groups, and food policy experts.

IMPORTANCE OF OVERSIGHT

FDA Relies Heavily on State Food Firm Inspections.

We found that in the past 3 years, States conducted through contracts and partnership agreements, on average each year, 61 percent of food firm inspections recorded in FDA's national database. Although traditionally States have focused heavily on low-risk food firms, increasingly, these State inspections are focused on high-risk food firms. Partnership agreements, which rely primarily on State authorities and resources, are becoming a significant source of food firm inspections. State inspections offer FDA an important source of industry coverage, as well as expertise.

States Vary Significantly in their Capacities to Conduct Inspections.

We identified five significant ways in which State inspections and food programs vary: inspection classifications, enforcement authorities, inspection authorities and regulations, inspector education and training, and time spent on inspections. These variations raise concern about the quality and uniformity with which FDA's food program is carried out.

Variation in State Regulatory Programs can Inhibit Commerce.

The variation in State laws and inspection practices adds complications, costs, and frustrations for food firms engaged in multi-State commerce. For our international trading partners, variation in State laws and inspection practices can undermine confidence in the uniformity of U.S. food safety standards and enforcement efforts.

FINDINGS

FDA's Oversight of State Food Firm Inspections is Limited.

Under contracts, FDA obtains minimal information to assess the quality of State food firm inspections.

FDA's on-site audits have declined. Over the past 5 years, the number of audits dropped 59 percent, from 253 in 1993 to 104 in 1998. In 1998, FDA district offices did not conduct a single audit in 21 of the 38 States holding contracts.

FDA's on-site audits provide a limited basis for assessing State performance. FDA relies primarily on independent audits, which focus on the accuracy of inspection findings but give little attention to how State inspectors drew conclusions. FDA's lack of documentation of State performance further limits the effectiveness of audits.

FDA's reviews of State contract inspection reports lack much rigor. FDA conducts minimal assessment of the quality of inspection reports submitted by States. In response to our survey, 14 of 17 FDA district offices overseeing contracts reported that they use no formal criteria to evaluate the quality of the reports.

FDA rarely seeks input from external sources to evaluate State performance. FDA takes little advantage of its public meetings, food safety hotlines, or food safety websites to solicit input from food firms, trade associations, or consumers about the quality of State inspections.

Under partnership agreements, FDA obtains even less information to assess the quality of State food firm inspections.

FDA does not audit State performance, but participates in some joint inspections with States. FDA and State officials regard joint inspections as a mechanism to provide on-site training for both Federal and State inspectors rather than as a tool to evaluate State performance.

FDA's reviews of State partnership inspection reports are even more limited than its reviews of contract inspection reports. States submit differing levels of information about partnership inspections, depending on the States' inspection resources, policies, and procedures. We found that FDA district offices often lacked enough information to assess the quality of inspections.

FDA provides limited feedback to States on the quality of their inspections.

The majority of FDA's ongoing feedback to States relies on informal communication and individual district office initiatives. FDA does not routinely provide States with written feedback on either its on-site audits or reviews of State inspection reports.

FDA's performance evaluations provide States with little feedback about the quality of State inspections. The majority of contract and partnership evaluations contain cursory and general comments with little meaningful assessment of States' performance. Furthermore, FDA rarely provides the evaluations to States.

FDA's feedback places little emphasis on improving the quality of State inspections. FDA's feedback is geared toward identifying deficiencies in food firm inspections rather than enhancing State performance. FDA does little to identify best practices among States and disseminate this information.

FDA provides limited feedback to the public regarding its oversight of contracts and partnership agreements.

FDA does not make information available about its reliance on State inspections or about State performance. Despite its extensive reliance on State inspections, it shares little information about the extent and nature of its reliance. Such information would provide an important source of FDA accountability to consumer, industry, and other groups.

FDA Faces Significant Barriers in Overseeing States

FDA's ability to conduct quality oversight depends largely on its own internal capacities. A number of barriers inhibit FDA's capacity to conduct effective oversight:

Low priority of food safety inspections. Without a statutory requirement to inspect a minimum number of food firms, FDA's resources to conduct food firm inspections has diminished. Within the food inspection program, FDA's resources to oversee State food firm inspections competes with its own resources to inspect food firms.

Limited leverage to oversee partnership agreements. The majority of FDA and State officials we spoke with underscored the fact that States are doing FDA a favor by helping the FDA to extend its inspection coverage at a very low cost. FDA's heavy reliance on States compromises its ability to be truly critical of these inspections.

Reduced training and agency expertise. Maintaining agency expertise is vital to effectively overseeing States. In the past decade, however, formal training has declined and FDA has lost field experience in States that inspect the bulk of the food firms.

Limited accountability of FDA district offices. FDA does little to assess the effectiveness of district offices in overseeing State inspections.

Lack of important enforcement authorities. FDA must rely on State enforcement authorities that it lacks, including the ability to revoke a firm's license, to immediately embargo food suspected of being adulterated, and to access all of a food firm's records without a Federal warrant. Several FDA and State officials have raised concerns that this reliance compromises FDA's ability to be critical of State inspections.

RECOMMENDATIONS

State governments play a critical role in ensuring the safety of the nation's food supply, both under their own authorities and in concert with FDA through contracts and partnership agreements. They provide valuable resources and expertise that serve as a complement to FDA's own inspection efforts. Our recommendations recognize and build on the importance of this State role.

For State inspections carried out under FDA auspices, it is essential that FDA provide effective oversight to ensure both the quality and uniformity of inspections. FDA brings important strengths to this oversight role through a tradition that emphasizes science-based research and a public health perspective. We offer seven recommendations, based on the following template, on how FDA can provide leadership to address the shortcomings we identified in its current system of oversight. FDA has already undertaken some recent initiatives in the direction we call for.

Template For Effective FDA Oversight of State Food Firm Inspections

- ✔ **Equivalency:** Equivalency among Federal and State food safety standards, inspection programs, and enforcement practices.
- ✔ **On-site Audits:** An effective on-site mechanism for evaluating State inspection performance.
- ✔ **Inspection Information:** Routine submission of standardized inspection information.
- ✔ **External Sources:** Information from varied external sources on State inspection performance.
- ✔ **Feedback to States:** Substantive and timely FDA feedback to States on inspection performance.
- ✔ **Internal Capacities:** Enhanced FDA capacities to conduct effective oversight.
- ✔ **Public Information:** Proactive public disclosure of FDA's reliance upon and oversight of State inspections.

We present our specific recommendations below. But first we offer a caution.

An Initial Caution: FDA Should Reevaluate Its Reliance on the Partnership Agreements as a Mechanism for Conducting Inspections.

Partnership inspections have grown to account for 43 percent of the State food firm inspections conducted in association with FDA. While many of the State inspections may well be of high quality, FDA is not in a position to adequately attest to the quality or uniformity of these inspections.

We believe that a two-tier system of FDA oversight, under which there is less oversight of partnerships than contracts, is inappropriate. As follows, we offer our recommendations as actions that FDA can take to oversee State inspections conducted through both the partnership agreements and contracts. FDA must be able to assure consumers, industry, and international trading partners that its commitment to quality and uniformity is independent of the mechanism through which inspections are conducted.

Recommendation 1. FDA Should Work with States to Achieve Basic Equivalency in Food Safety Standards and Laws, and in Inspection Programs and Practices.

- Pilot test a system audit as a mechanism to foster equivalency and evaluate State capacity and performance.

Recommendation 2. FDA Should Devote High Priority to Improving its On-Site Audit Mechanism for Evaluating the Effectiveness of State Inspections.

- Stress joint audits rather than independent audits.
- Develop guidance for effective on-site audits.
- Determine the appropriate minimum frequency for on-site audits.

Recommendation 3. FDA Should Require that States Routinely Provide FDA with Standardized Information on the Inspections They Conduct.

- Define a core set of information to collect from States about food inspections.
- Provide guidance on the extent and nature of inspection report reviews.

Recommendation 4. FDA Should Draw on Multiple External Sources of Information in Assessing State Inspection Performance.

- Solicit feedback from industry, consumer, and other groups on the adequacy of State inspections.

Recommendation 5. FDA Should Provide Substantive and Timely Feedback to States on Their Inspection Performance.

- Provide States with ongoing and written feedback from on-site audits.
- Provide States with periodic evaluations assessing overall performance.
- Promote information exchange on promising approaches of State programs.

Recommendation 6. FDA Should Enhance Its Internal Capacities to Conduct Effective Oversight.

- Ensure inspector competence in both inspection and audit functions.
- Hold district offices more accountable for conducting effective oversight.
- Ensure the systematic identification of all food firms in interstate commerce.
- Seek broader FDA enforcement authorities.

Recommendation 7. FDA Should Increase Public Disclosure of Its Oversight of State Food Firm Inspections.

- Make more explicit information available about FDA's reliance upon States and its oversight of State inspections.

COMMENTS ON THE DRAFT REPORT

We received written comments on the draft report from the Food and Drug Administration, the Association of Food and Drug Officials, the National Food Processors Association, the National Fisheries Institute, and the Center for Science in the Public Interest. In general, the report received wide support among each of the groups. In the body of the report, we summarize the major comments and offer our responses. We incorporated several changes recommended by these groups in the text of the final report. The full text of each set of comments is included in appendix M.

The Food and Drug Administration

The FDA welcomes our report as a tool to strengthen Federal oversight of State food safety inspections. The FDA agrees with the majority of our recommendations and points to a number of recent initiatives underway that move in the direction we call for. The FDA does not agree with our recommendation to solicit external information sources in assessing State performance. The agency believes that its own audit process is the best way to assess State performance. The agency also does not address our specific recommendations about increasing public disclosure of information regarding FDA oversight and State performance. Regarding oversight of the partnership agreements, the FDA agrees that it must "fundamentally modify the nature of these agreements."

We recognize that FDA is dealing constructively with many of the shortcomings we identify in our report. We encourage the agency to continue to do so. We also urge the agency to reconsider the value of external sources of information in assessing State performance. We continue to believe that such information can serve as an important complement to FDA's own audit information. On the matter of publicly disclosing information, we urge FDA to take immediate action to post the performance information we recommend. Such information could include identification of the States with which FDA holds a contract or partnership, the number and types of inspections under each arrangement, the ratio of FDA-to-State inspections in particular States, and the FDA's assessments of State performance through audits or periodic performance evaluations.

External Organizations' Comments

The external parties express support for the major thrust of our findings and recommendations. Each group also raises several concerns. The Association of Food and Drug Officials (AFDO) emphasizes the expertise of many State programs and questions whether all FDA district offices are currently in a position to adequately judge the quality and uniformity of State inspections. The AFDO also underscores the work of the Roles and Responsibilities work group within the National Food Safety System (NFSS) project as an important reference point that FDA may want to consider in redesigning its oversight of State food firm inspections.

The two industry groups, the National Food Processors Association (NFPA), and the National Fisheries Institute (NFI), express particular support for our recommendation to incorporate feedback from external parties in the evaluation of State programs. The NFPA urges that our recommendations go further by also including feedback from external parties on the performance of Federal inspections. Neither group agrees with our recommendation to provide FDA with additional enforcement authorities. The groups believe that the current system of relying on State authorities for enforcement has worked well. The Center for Science in the Public Interest (CSPI) strongly supports our report, but does not feel that we went far enough with our recommendations. The CSPI's comments point out vulnerabilities and potential weaknesses in State inspection programs, such as the potential influence of State politics and economics on regulatory oversight. The group suggests that FDA should restrict reliance on States to low-risk inspections.

We are pleased with the broad support from each of the external parties for the major thrust of the findings and recommendations in our report. On the matter of State and Federal expertise, we believe that AFDO raises an important point regarding the variation in food safety expertise and inspection and audit practices among FDA district offices. We recommend that FDA ensure inspector competence in both inspection and audit functions. Such expertise is critical to the credibility of the oversight process. We also recognize the current work underway through the NFSS project and we have modified the text of our report to more fully reflect this work. Regarding concerns with our recommendation to provide FDA with additional enforcement authorities, we continue to believe that these authorities are a vital component of effective oversight. We, along with other groups, raise concern that FDA's reliance on States to take enforcement actions may compromise FDA's ability to be critical of States' performance. On the issue of Federal reliance on State inspections, we do not seek to determine what would be an appropriate balance of inspection duties among Federal and State governments. However, we do emphasize that FDA should assure consumers that its commitment to food safety is no less under partnerships than it is under contracts.